



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Dear Medical Device Manufacturer:

NOV 1 2000

The Center for Devices and Radiological Health (CDRH) is always looking for ways to improve the training opportunities available to our employees.

During a recent Center-wide training needs assessment, employees said they wanted a better understanding of how medical devices were used in actual clinical settings. One mechanism we believe would help achieve this goal is to obtain videotapes illustrating such use. We understand that medical device manufacturers and clinicians often produce such videotapes for training purposes, viewing at medical/scientific meetings, etc. Since these training tools would be of great benefit to our employees, and industry would indirectly benefit from this educational effort in that CDRH staff will further enhance their device knowledge, we would appreciate hearing from firms that would be willing to lend us such videotapes.

To provide a meaningful training experience for CDRH staff, it would be helpful if the videotapes could meet some or all of the following criteria:

- Focus on device application in clinical use.
- Present information consistent with approved labeling (e.g., indications).
- Information regarding patient selection, device design and description, human factors considerations, associated surgical procedures (if applicable), device setup/preparation, cleaning/ maintenance, patient information, and other relevant information would be helpful, but it is not critical that all these elements necessarily be addressed in each tape.
- Include narration in appropriate detail for a knowledgeable audience.
- Be in VHS format.
- Be primarily non-promotional in nature.
- Have duration appropriate to content (typically 10-30 minutes).
- Be accompanied by a brief written description of the videotape's content and length, and any other information that might enhance the training experience or that our staff should be aware of (e.g., early prototype shown, investigational device, etc.).

Our plan is to air the videotapes over CDRH's closed circuit TV network on a regular basis, grouped by product specialty. We are interested in new as well as more conventional medical device technologies, in all product areas.

If you would like to lend videotapes for this purpose, please send them to my attention at 16071 Industrial Drive (HFZ-213), Gaithersburg, MD 20877. If you have any questions, please contact me at (301) 827-3623, or by email at mdk@cdrh.fda.gov. Thank you in advance for your assistance.

Sincerely yours,

Mark D. Kramer

Mark D. Kramer
Director
CDRH Staff College